April 30, 2018

Mazor Robotics Ltd.
℅ Ahava Stein
Regulatory Affairs Consultant
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as St.
Kfar Saba, 44425
Isreal

Re: K180307
Trade/Device Name: Mazor X
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, HAW, LLZ
Dated: March 11, 2018
Received: March 14, 2018

Dear Ahava Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180307

Device Name
Mazor X

Indications for Use *(Describe)*

The Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal and brain surgery. It may be used in either open or minimally invasive or percutaneous procedures.

Mazor X 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SUMMARY OF SAFETY AND EFFECTIVENESS

K180307
(Premarket Notification [510(k)] Number)

1. Submitter Information

Manufacturer Name and Address
Mazor Robotics Ltd.
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5 Shacham St.,
Caesarea Park North 3088900,
Israel

Official Correspondent
Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as St. (Beit Hapaamon, Suite 102)
Kfar Saba 4442520,
Israel

2. Date Prepared: April 22, 2018

3. Device Name Mazor X

Proprietary Name: Mazor X

Common Name: Combination of:
1. Stereotaxic instrument; and
2. System, Image Processing, Radiological

FDA Classification Name: 21 CFR 882.4560; Stereotaxic instrument

FDA Classification: Class II, Product Code OLO, HAW and LLZ

4. Predicate Devices

The Mazor X is substantially equivalent to the following device:

Manufacturer	Device	510(k)	Date Cleared
Mazor Robotics Ltd.	Mazor X System	K163221	April 04, 2017

5. Device Description

The Mazor X hosts guidance for spine and brain procedures and intra-operative 3D image processing capabilities. It enables the surgeon to precisely position surgical instruments and/or implants (in spinal surgery). The planning of the surgical procedure and virtual placement of surgical instruments and/or implants (e.g., a screw) can be achieved through pre-operation planning based on the patient's CT scan or intra-operative planning based on Mazor X 3D Scan image or on a 3D image uploaded from an external 3D image acquiring system. The Mazor X enables accurate deployment of surgical accessories in the precise anatomical location according to predefined planning. With the imaging capabilities of the system, the user can also visualize the implants on the patients CT. The Mazor X is a device modification of the original Mazor X System cleared in 510(k) K163221.

6. Indications for Use

The Mazor X is indicated for precise positioning of surgical instruments or spinal implants during general spinal and brain surgery. It may be used in either open or minimally invasive or percutaneous procedures.

Mazor X 3D imaging capabilities provide a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the Mazor X.

8. Performance Testing

The following Performance tests were performed on the Mazor X system:

- Software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (May 11, 2005) and the IEC 62304 Standard for Medical Device Software - Software Life Cycle Processes. The software validation tests demonstrate that the Mazor X software version meets the design requirements. Test cases were designed for testing procedure simplicity, system startup, security, user interfaces, diagnostics and error handling, performance and robustness, installation, and database.
- The modified Mazor X Align module was retested according to the same functionality testing as the original Mazor X Align module and included the following validation testing:
  - Testing the registration algorithm to validate the changes related to updating the CT based fluoroscopy images and the pre-operative registration method (CT-X-ray).
  - Validation of lateral positioning.
  - Validation of the modifications to the vertebral end-plates recognition algorithm.
  - Integration testing of the modified Mazor X System.

9. Technological Characteristics Compared to Predicate Device

The device modifications included modified software with minor software changes and a slightly modified Mazor X System (minor hardware changes). The software changes included SW optimization within the established specifications, enhanced functionalities (e.g., updating CT based fluoroscopy images and pre-operative registration method (CT-X-ray), support of lateral approach and modifications to the vertebral end-plates recognition algorithm), as well as screen enhancements (graphical enhancements and enhanced information presented on screen). The modified Mazor X workstation and Surgical System are very similar to the Mazor X workstation and Surgical System with some minor technical and design improvements to allow better manufacturability during assembly process.

The modifications do not adversely affect the safety, effectiveness and performance of the Mazor X system. The Mazor X system was tested according to the aforementioned validation and performance tests and found compliant.

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the indications for use of the Mazor X system are substantially equivalent to the predicate device cited above.

10. Conclusion

The performance testing and comparison to the predicate device demonstrate that the Mazor X system is as safe, as effective and performs as well as the legally marketed Mazor X System predicate device. Therefore, the Mazor X system is substantially equivalent to the Mazor X System cleared under K163221.